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4

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Signed J Evans.

Dated - 7 AUG 2000

Patents Form 1/77

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The Patent Office

Request for grant of a patent

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The Patent Office

Cardiff Road
Newport
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1. Your reference — P23782/CMC/GWO

2. Patent application number *(The Patent Office will fill in this part)* — 06 MAY 1999 — **9910323.6**

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

University of Ulster
Faculty of Engineering
Newtownabbey
County Antrim, BT37 0QB

Patents ADP number *(if you know it)* 5905918004

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention — "Cardiac Defibrillation"

5. Name of your agent *(if you have one)* — Murgitroyd & Company

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

373 Scotland Street
Glasgow
G5 8QA

Patents ADP number *(if you know it)* — 1198013

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	–
Description	6
Claim(s)	–
Abstract	–
Drawing(s)	2 + 2

10. If you are also filing any of the following, state how many against each item.

Priority documents	–
Translations of priority documents	–
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	–
Request for preliminary examination and search *(Patents Form 9/77)*	–
Request for substantive examination *(Patents Form 10/77)*	–
Any other documents *(please specify)*	–

11. I/We request the grant of a ~~patent~~ on the basis of this application.

Signature MURGITROYD & COMPANY Date 5.5.1999

12. Name and daytime telephone number of person to contact in the United Kingdom: Graham Wotherspoon 0141 307 8400

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Notes

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Cardiac Defibrillation

This invention relates to cardiac defibrillation, and in particular (but not exclusively) to an apparatus for delivering an electrical defibrillating signal to a human heart in the state of atrial fibrillation (AF), using transdermal energy transfer to a passive implanted device.

Atrial fibrillation is a common heart arrhythmia that increases in prevalence with age, with typically 10% of people over the age of 70 experiencing an incident. The process of cardioversion of AF to normal sinus rhythm (SR) has traditionally been attempted by pharmacological measures or transthoracic direct current shock. The former has been limited by variable cardioversion rates and the risk of side effects, in particular proarrhythmia. The latter requires sedation or anaesthesia and high energy shocks, and there is a high recurrence rate. For these reasons, there has been interest in catheter-based transvenous atrial defibrillation and its potential use in an implantable atrial defibrillator. However, atrial implantable defibrillators are complex devices requiring on-board pattern recognition with complex recording and follow-

up procedures. The need for electrical charging circuitry using active devices adds to the complexity and weight of the implant.

The present invention provides an apparatus for cardiac defibrillation which comprises an external circuit and an implantable circuit; the external circuit including an induction transmitting coil and signal generating means for applying radio frequency pulses of predetermined shape to the transmitting coil; the implantable circuit including an induction receiving coil for receiving pulses when the two coils are in proximity, and a rectification circuit having an input connected to the receiving coil and an output driving electrodes implantable in the heart.

In a preferred form of the invention, for use in atrial defibrillation, the power transmitted per pulse is less than about 5J and the radio frequency is in the range 3-30 MHz, typically about 7MHz.

The signal generating means suitably comprises a radio frequency generator switched or gated under the control of a pulse generation and shaping means which in turn is responsive to an ecg synchronisation signal. The ecg synchronisation signal may be provided via a telemetry transmitter implanted in the patient.

The external circuit may further include a telephony link by which the ecg may be transmitted to, and/or the apparatus controlled from, a remote location.

The external and implantable circuits preferably include impedance matching components, typically capacitors, to achieve a high degree of tuning.

The inductive coupling will typically be tuned to resonance, preferably by use of series resonance in the external circuit and parallel resonance in the implantable circuit.

Most preferably, the implantable circuit contains only passive components.

From another aspect the invention provides a method of cardiac (preferably atrial) defibrillation which comprises transmitting pulses of controlled shape and energy transdermally by high frequency magnetic induction to a substantially passive implanted circuit which includes electrodes implanted in the heart.

It is known to transfer energy transdermally by induction, but only for purposes of recharging batteries in implanted devices such as pacemakers or continuously powering implanted devices such as pumps. It has not hitherto been proposed to use such techniques to transfer controlled waveforms for high-energy physiological stimulation.

An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows the elements required for controlled, transdermal energy delivery to a cardiac load;
Figure 2 illustrates the circuitry required external to the body; and
Figure 3 represents the body-internal circuitry.

In the apparatus (Figure 1), an appropriately synchronised trigger pulse is firstly generated, based on the subject's electrocardiogram (ecg). This pulse,

after shaping to a waveform 1 suitable for AF conversion, is used to amplitude modulate a radio frequency (RF) carrier generator 2 at a power level consistent with the transmission of 1-5 J of energy to the internal load, itself nominally 50 Ω resistive. The transmission path takes the form of a pair of coaxially-aligned transmit 3 and receive 4 inductors constructed in the form of an RF transformer. The diameters of the coils 3 and 4 are set so as to optimise energy transfer at a physical spacing not less than the thoracic wall's thickness. Both inductors are wound with enamelled copper wire. The transmitting coil 3 is mounted on an insulated paddle to facilitate adjustment in its placement on the subject's body. The implanted circuitry is mounted on a printed circuit board and consists of the receiving coil 4 connected to impedance matching, rectification and wave-shaping components 5. The final defibrillating signal is connected to the heart 6 by catheters 7, one placed in the lateral right atrium (RA) and the other in the distal great cardiac vein via the coronary sinus. Alternatively, any conventional atrial defibrillation delivery system may be used.

In one example, the coils 3 and 4 are designed to give optimum inductive coupling at a centre-to-centre spacing of 20mm. Given a maximum diameter of for practicability the receiving coil 4 of 35mm, the transmitting coil 3 has a diameter of 53mm. Both inductors are wound with 1.5mm enamelled copper wire. The transmitting coil 3 is arranged as a solenoidal coil, spaced at one turn. The receiving coil 4 is pile-wound to conserve space in the final implant.

Both inductors in the apparatus are tuned to resonance at the selected operating frequency of the system,

typically in the range 3-30 MHz. The transmitter uses series tuning by capacitor 9 (Figure 2), whilst the receiving coil 4 is parallel-tuned, with capacitive matching to the load 10 (Figure 3), by means of capacitors C1 and C2. A radio-frequency choke 11 provides a DC path for rectifier current.

Pulse widths will typically be in the range 6-60ms. Single pulses are usually applied in a clinical situation.

Optionally, as shown in Figure 1 a telemetry link 8 may be incorporated to provide ecg monitoring and feedback-derived, automatic tuning of the energy delivery system. Such a link may also be powered from energy delivered transdermally, by using a low-power transfer to power up the telemetry link, or to charge an on-board battery. Alternatively, the ecg could be transmitted via the induction coils using a suspended carrier technique.

As is also indicated in Figure 1, the external circuitry may include a remote communication link, which may be via telephone communication (landline or GSM) or via a radio link. This would, for example, enable the patient's ecg to be transmitted to a hospital for monitoring and for inspection by a physician. Defibrillation could be activated remotely, and spoken instructions could be conveyed to the patient.

Atrial defibrillation currently requires a pulse energy of about 3 to 4J. By using a tuned inductive coupling as described, typically at a frequency about 7 MHz, these energy levels can be transmitted transdermally while maintaining control of pulse shape and timing.

It is contemplated that by refining the pulse shape, duration and timing required to achieve defibrillation the energy necessary could be reduced to 1J or less, which would be painless to the patient and remove any need for sedation.

The pulse form shown in Figure 1 is a biphasic pulse, which is the form we currently prefer. However, other pulse forms and hence RF envelope shapes may also be used, such as monophasic and multiple.

Although described above with particular reference to atrial defibrillation, the invention could find use in ventricular defibrillation. Here, though, the required energy levels are much higher (typically about 15J).

It will be appreciated that one of the benefits of the embodiment described is that the implanted hardware is entirely passive and does not require any implanted power source. However, the invention does not exclude the possibility of some active components being implanted, with a reduced requirement for an internal source of power.

Other modifications may be made within the scope of the present invention.

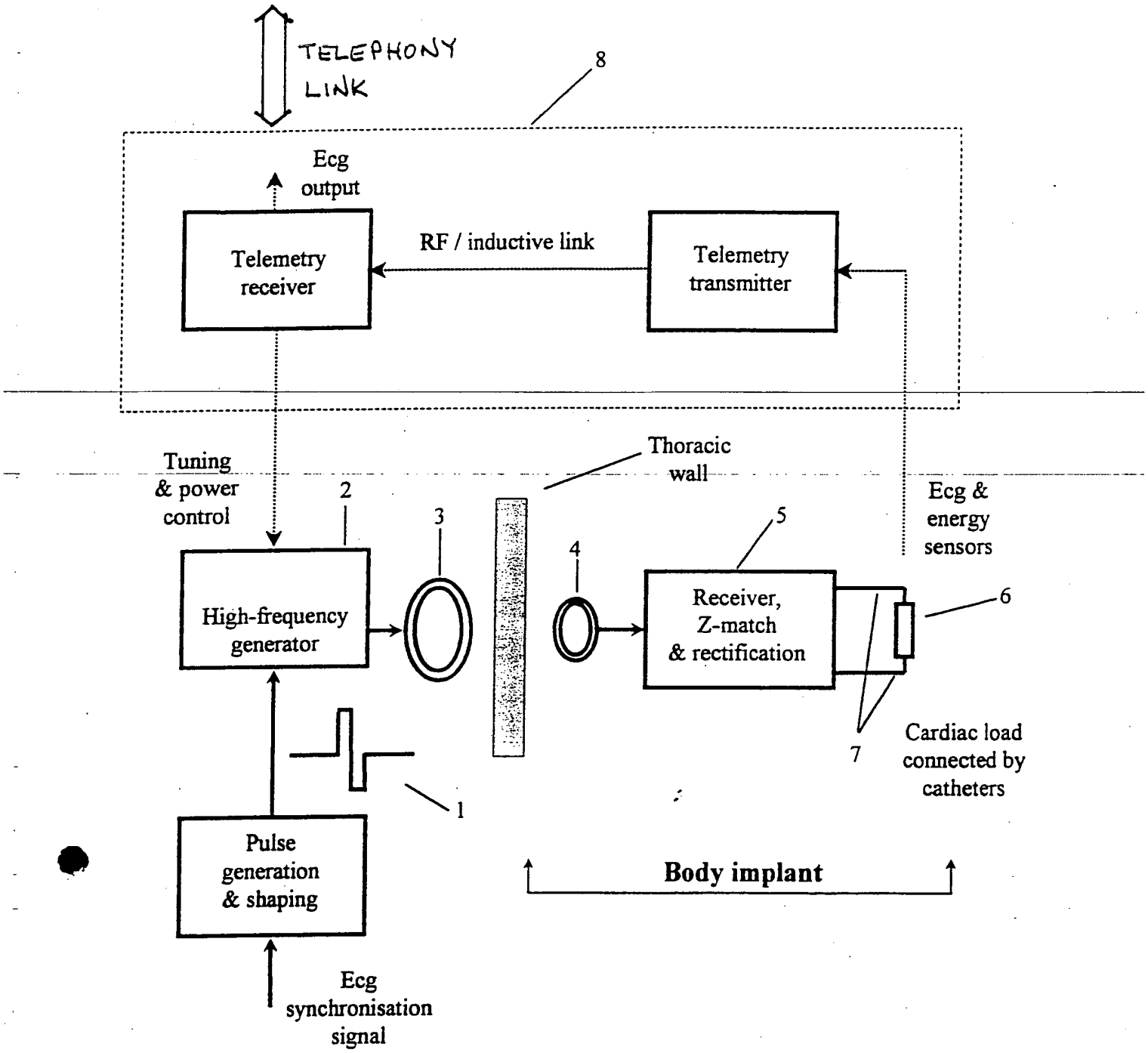
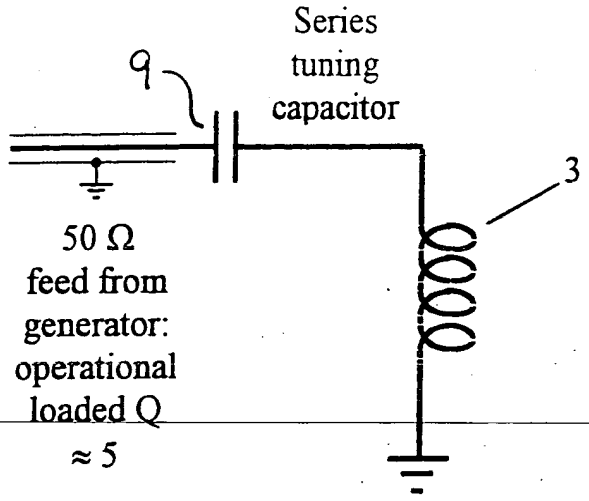

TELEPHONY LINK
8
Ecg output
Telemetry receiver
RF / inductive link
Telemetry transmitter
Tuning & power control
2
3
Thoracic wall
4
5
Ecg & energy sensors
High-frequency generator
Receiver, Z-match & rectification
6
7
Cardiac load connected by catheters
1
Pulse generation & shaping
Body implant
Ecg synchronisation signal

Fig.1.


Series
tuning
capacitor
9
3
50 Ω
feed from
generator:
operational
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≈ 5

Fig. 2.

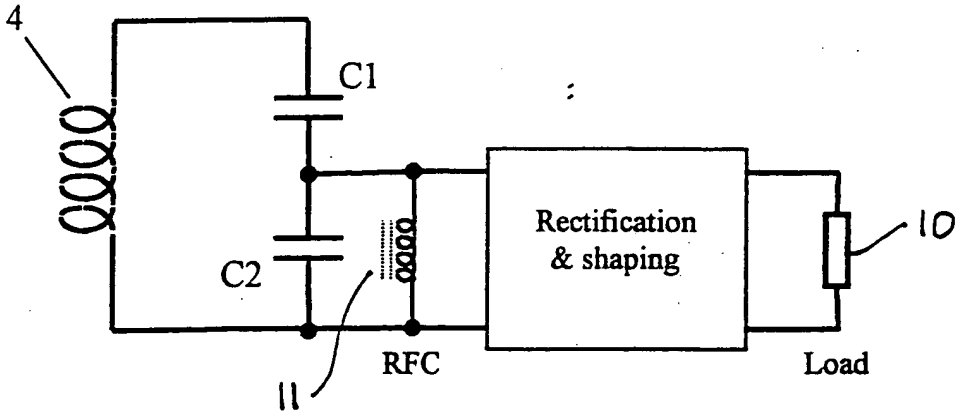
4
C1
C2
11
RFC
Rectification
& shaping
10
Load

Fig. 3.